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10/766,020	01/29/2004	Joyce Taylor-Papadimitriou	TAYLOR=1G	2262

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,020	TAYLOR-PAPADIMITRIOU ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *25-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/29/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-31 are all the pending claims for this application.

Election/Restrictions

2. Applicant's election with traverse of Group I (Claims 1-24) in the reply filed on May 24, 2006 is acknowledged. The traversal is on the ground(s) that the elected product claims are allowable thus the method claims should be rejoined. This is not found persuasive because claims 1-24 of Group I are not patentable for reasons given below. See MPEP 821.04 for rejoining of process claims for an allowable product.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-24 are all the pending claims under examination. Claims 25-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 7 and 18 reciting the hybridization conditions are part of the original disclosure, and the hybridization conditions for identifying any nucleic acid encoding a human polymorphic epithelial mucin sequence and to which the SM-3 antibody binds is critical or essential to the practice of the invention, but is not disclosed in the remainder of the specification (In re Benno 768 F.2d 1340, 226 USPQ 683 (Fed.

Cir. 1985) and MPEP 608.01(o)). Applicants are requested to amend the specification to include the claimed subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 7, 10, 11, 15, 16, 18 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1, 7, 11, 15 and 24 are indefinite for the recitation "a polypeptide comprising the core protein of a human polymorphic epithelial mucin" as the scope encompasses the full-length protein and any fragments thereof. The specification defines only 7 DNA clones and all of which encode fragments of the full-length protein (FIG. 11) [0134]. See further rejections set forth below.

b) Claims 7, 11, 16 and 18 recite the limitation "the DNA of a)" in reference to the complementary DNA sequence of II). There is insufficient antecedent basis for this limitation in the claim.

c) Claims 10 and 24 are indefinite for the recitation "said coding sequence being obtainable by screening" as the term "obtainable" does not positively recite that the coding sequence can be detected by screening or isolated from a cDNA library derived from human breast cancer cell line MCF-7 much less that Applicants have actually

isolated any such coding sequence. The term is indefinite because it does not set forth the metes and bounds of the coding sequence.

d) Claims 11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are the hybridization temperature for the hybridization conditions.

e) Claim 24 is indefinite for the phrase "identified by hybridization" as the conditions for hybridization or specific stringency are not defined in the specification: the reference to "ref 34" (Young and Davis in Genetic Engineering) at p. 19 does not provide any particular set of conditions and one of skill in the art would not be able to determine what conditions, and thus, what molecules Applicant intended the claim to encompass. Since the specification does not provide an unambiguous definition for the term, the metes and bounds of the claimed invention cannot be determined.

Biological Deposit Requirement

6. Claims 1-24 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (a) known and readily available to the public; (b) reproducible from the written description.

a. It is unclear if a hybridoma cell line which produces an antibody having the

exact chemical identity of the SM-3 monoclonal antibody is known and publicly available, or can be reproducibly isolated without undue experimentation. The Examiner's search of the ATCC website did not identify a hybridoma deposit under SM-3. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

b. For example, very different V_H chains (about 50% homologous) can combine with the same V_K chain to produce antibody-binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_K sequences to produce antibodies with very similar properties. The results indicate that divergent variable region sequences, both in and out of the complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. [FUNDAMENTAL IMMUNOLOGY 242 (William E. Paul, M.D. ed., 3d ed. 1993)]. Therefore, it would require undue experimentation to reproduce the claimed antibody species SM-3. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

7. Claims 15-23 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (a) known and readily available to the public; (b) reproducible from the written description.

a) It is unclear if a plasmid-DNA clone, having the exact chemical identity of pMUC10 is known and publicly available, or can be reproducibly isolated without undue experimentation. The Examiner's search of the ATCC website did not identify a DNA clone deposit under pMUC10. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above vector, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (a) the claimed vector; (b) a bacterial cell line which produces the chemically and functionally distinct vector claimed; and/or (c) the claimed vectors nucleic acid sequence is an unpredictable event.

b) The specification lacks deposit information for the deposit of the pMUC10 clone. It is unclear whether clones possessing the identical properties of this clone are known and publicly available or can be reproducibly isolated from nature without undue experimentation. With respect to pMUC10 clone, there is no indication in the specification that the vector is readily available to the public and the specification does not provide any guidance or direction to assist one skilled in the art to make and/or use this vector. Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the pMUC10 clone, a suitable deposit is required for patent purposes, evidence of public availability of the claimed clone pMUC10 or evidence of the reproducibility without undue experimentation

of the claimed vectors, is required. Deposit of the pMUC10 clone would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

8. If the deposit for either the hybridoma or the pMUC10 DNA clone is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-24 are drawn to a genus of expression vectors and nucleotides encoding a polypeptide comprising the core protein of a human polymorphic epithelial cell mucin protein and that binds to the SM-3 Mab. The genus of vectors and nucleotides includes large numbers of unpredictable species comprising the full length protein, polymorphic forms, and fragments thereof, and the specification fails to support all of these embodiments.

The specification teaches screening a cDNA library made from size selected MCF-7 mRNA with a polyclonal antiserum made to the purified milk mucin core protein which had been stripped of its carbohydrate, and from which 7 cDNA clones comprising human polymorphic epithelial mucin were selected [0131]; expressing the 7 clones as fusion proteins and probing the fusion proteins with a variety of antibodies to the stripped mucin, including the polyclonal antiserum which was used initially to select the clones and a cocktail of SM-3 and SM-4 [0132]; inserts from the lambda clones are designated pMUC3-10, and the 7 clones were compared to each other for sequence

homology. The largest cDNA insert from pMUC10 was used to probe the inserts and found to hybridize to all 6 inserts (FIG. 11) [0134]; as shown by agarose gel electrophoresis (FIG. 11), the inserts vary in size from about 200 to up to about 1800 bp. The largest insert from pMUC10 has been used as the hybridization probe in all subsequent experiments [0135]; and most significantly, that **the cDNA clones represent a portion of the gene** coding for the human mammary mucin which is expressed by differentiated breast tissue as well as by most breast cancers [0143]. The specification does not provide sufficient written description as to all the embodiments encompassed by a polypeptide comprising a human polymorphic epithelial mucin having the property of binding SM-3 antibody.

A "representative number of species" means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]. " See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus

by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)(Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.).

The specification does not teach an expression vector or nucleotide encoding any full-length size protein. Furthermore, the priority of the instant application goes back to 1987 and it appears that that the chemical structure of a DNA molecule encoding the full size core protein of a human polymorphic epithelial mucin was not known until 1990 when Marjolijn et al (J Biol Chem vol. 265, pages 5573-8 (1990) cited in the IDS of January 1, 2004); Larocca et al. (Cancer Res. 50(18):5925-30 (1990)); and Gendler et al. (J. Biol. Chem 265:15286-93 (1990)) published the full length structure. Note that Gendler and Spicer (Annu Rev Physiol 57: 607-34 (1995)) teach the general state of art about the discovery of mucin sequences and genetic polymorphisms associated with the sequence.

It is apparent that Applicants were not in possession of all the species of the claimed genus for expression vectors or nucleotides encoding DNA for the full length or just any portion of the human polymorphic epithelial cell mucin protein. The claims encompass a genus for the full-length core protein as well as the unpredictable sequences taught by Marjolijn, Larocca, Gendler and Gendler and Spicer, and other

DNA molecules encoding a varied repeat sequence due to allelic variances in the repeat sequence. Therefore the full breadth of the claims do not meet the written description provision of 35 U.S.C. § 112, first paragraph.

10. Claims 7-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making vectors and nucleotides encoding sequences for human polymorphic epithelial mucin (hPEM) with an SM-3 Mab binding segment (i.e., pMUC3, pMUC4, pMUC5, pMUC6, pMUC7, pMUC8, pMUC9 and pMUC10) and using the pMUC10 insert (1800 bp) as a hybridization probe to select other nucleotides comprising hPEM, does not reasonably provide enablement for a) using the pMUC3, pMUC4, pMUC5, pMUC6, pMUC7, pMUC8, pMUC9 and pMUC10 vectors, b) making vectors and nucleotides comprising encoding a full-length human polymorphic epithelial mucin sequence and just any polymorphic form and/or fragment thereof to which the SM-3 antibody binds, c) screening non-specific nucleotides encoding a cross-reactive polypeptide comprising a core protein for a repeat sequence from a nucleotide encoding hPEM based on hybridization to the repeat sequence alone i.e., the DNA sequences I and II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any vector and any nucleotide encoding a polypeptide comprising a core protein for a repeat sequence like the core protein of hPEM, where the SM-3 antibody binds to the repeat sequence, and the vector or

nucleotide hybridize to one of DNA sequences I or II, where the vector comprises a promoter sequence operably linked to the nucleotide sequence.

See the interpretation of the specification as discussed under section 9, supra. The specification demonstrates the hybridization of the pMUC10 insert (1900 bp) to the 6 other clones (partial fragments of hPEM) without disclosing the specific hybridization conditions. Also, each of the original clones were from a lamda library previously selected with a polyclonal antiserum against purified hPEM protein. Thus the specification demonstrates that only the entire pMUC 10 insert can be used as a probe to identify other hPEM nucleotides. Applicants have not demonstrated that a probe comprising any one of the DNA sequences I or II alone, can be used to screen or identify a hPEM DNA molecule much less any coding sequence comprising a core protein for a repeat sequence like the core protein of hPEM. Additionally, in the absence of any examples, it is not apparent how one of skill in the art can practice the invention in order to obtain a vector or nucleotide encoding a polypeptide with any use. The specification does not enable one of skill in the art to use the pMUC3-10 molecules beyond purposes of screening, and it is not apparent what any newly isolated molecule comprising/encoding a core protein for a repeat sequence like the core protein of hPEM could be used for. Finally, because it is recognized in the art as discussed supra, that the mucin gene expresses numerous polymorphic fragments with allelic variation(s) in the repeat segments, it is not apparent to what extent the hybridization conditions or SM-3 binding property would allow one of skill in the art could identify the genus of molecules encompassed by the claims.

The claims are not commensurate in scope with the enablement provided in the specification. The specification does not support the broad scope of the claims which encompass all modifications to the nucleotide sequence encoding a polypeptide a core protein for a repeat sequence like the core protein of hPEM because the specification does not disclose the following:

The general tolerance to modification and extent of such tolerance;

The specific positions and regions of the sequence(s) which can be predictably modified and which regions are critical; and

The specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed vectors and nucleotides in a manner reasonably correlated with the scope of the claims broadly including any number of additions, deletions, or substitutions. The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 19 24 (CCPA 1970).

Without such guidance, the changes which can be made in the nucleotide structure and still maintain biological activity (i.e., binding to SM-3 antibody) is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F,2d 1200, 18 USPQ 1016 (Fed. Cir. 1991) at 18 USPQ 1026 1027 and Ex parte Forman, 230 USPQ 546 (BPAI 1986).f

Further protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by a glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al, Journal of Cell Biology Vol 111 November 1990 2129-2138). In transforming growth factor alpha, replacement of aspartic acid at position 47 with asparagine, did not affect biological activity while the replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (see Lazar et al Molecular and Cellular Biology Mar 1988 Vol 8 No 3 1247-1252).

Replacement of the histidine at position 10 of the B-chain of human insulin with aspartic acid converts the molecule into a superagonist with 5 times the activity of nature human insulin. Schwartz et al, Proc Natl Acad Sci USA Vol 84:6408-6411 (1987). Removal of the amino terminal histidine of glucagon substantially decreases the ability of the molecule to bind to its receptor and activate adenylate cyclase. Lin et al Biochemistry USA Vol 14:1559-1563 (1975).

These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of the protein.

Therefore, in view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the myriad of molecules encompassed in the scope of the claims, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,054,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because "the core protein of a human polymorphic epithelial mucin" is an obvious embodiment of "an antigen which comprises an antigenically active segment...of a tandem repeat sequence of the core protein of a human polymorphic epithelical mucin.. ."

Claim 2 is rejected over Claim 2 of US Patent No. 6,054, 438 as being identical and therefore obvious for the expression vector comprising the segment of at least ten consecutive amino acids in length.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER